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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,038	03/11/2004	Paul T. Gardiner	03-490.000008.	6719
5514 7590 10/21/2008 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112				
EXAMINER CHOI, FRANK I				
ART UNIT		PAPER NUMBER		
1616				
MAIL DATE		DELIVERY MODE		
10/21/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/799,038

Applicant(s)

GARDINER ET AL.

Examiner

FRANK I. CHOI

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 98,102-105 and 108-118 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 98,102-105 and 108-118 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/1/2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 98, 102-105, 108-118 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims have been amended to indicate that the composition of the method contains a protein in which the source of the protein is milk whey. However, the Applicant does not cite what disclosure in the Specification supports the amendment and "milk" in relation to whey does not appear to be specifically disclosed in the Specification. Since "whey", as indicated below, does not require that the source be from milk, said term is not sufficient to support the addition of "milk" to the claims. As such, the amendment of the claims to include "milk" appears to constitute new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 98, 102-105, 108-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabor (US Pat. 6,482,448) in view of Hastings et al. (US 2001/0041187), Miller et al. (US Pat. 6,019,999), Ostlund et al. (US Pat. 5,550,166), Shimizu et al. (US Pat. 6,004,926), Goldberg et al., and Goldberg.

Tabor discloses a dietary supplement which comprises a soy formulation and preferably comprising 70-90%, by weight, protein, 1-5%, by weight fat, and 1-25%, carbohydrate which may in the form of a powder or liquid form (Column 6, lines 15-46).

Hastings et al. discloses a performance-enhancing supplement in powder form which can be mixed with juice, water, milk or any other drinkable non-alcoholic beverage with the recommended daily serving being about 26 grams to about 78 grams in which the major ingredient is soy protein (Paragraphs 0006, 0007). It is disclosed that the supplement contains an amino acid premix of l-leucine, l-glutamine, l-alanine, glycine, l-arginine, l-lysine and that glutamine promotes anabolic conditions in muscle cells, increase rate of protein and glycogen synthesis, and indirectly promotes muscle growth, that alanine is an important source of energy for muscle tissue and that arginine is essential for optimal muscle growth and tissue repair (Paragraphs 0008-0010). It is disclosed that the supplement contains fat in the form of medium chain triglycerides with improve the absorption of the amino acids (Paragraph 0012) It is disclosed that the dietary supplement should include carbohydrate which supplies an energy

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source (paragraph 0014). It is disclosed that L-carnitine is added as it has been shown that athletes who supplement their diet with the same convert fat to energy more efficiently (Paragraph 0017). It is disclosed that creatine is included in the dietary supplement to shorten the time necessary for the body to generate replacement creatine phosphate and significantly reduce muscle recovery time between short duration, high intensity activities (Paragraph 0016). It is disclosed that individuals on an intense physical training regiment will gain optimal results at the higher levels of consumption whereas those on moderate or casual workout regimens will require less (Paragraph 0006).

Miller et al. discloses that for resistance-trained athletes the intake for protein should be approximately twice the normal RDI and that a preferred source of animal protein is dairy whey (column 1, lines 60-68, Column 2, line 1). A liposomal, ion-exchange whey protein is disclosed which is effective in increasing lean body mass, muscle mass with appropriate exercise and improving exercise performance (column 7, lines 46-60).

Ostlund et al. disclose that pinitol and derivatives and metabolites thereof are useful in nutritional composition for treating conditions associated insulin resistance including complications arising from athletic activity (Abstract). It is disclosed that inositol compounds improve insulin sensitivity (Columns 2, 3).

Shimizu et al. disclose a supplement containing protein, fat and carbohydrate which is ingested before, during and/or after exercise, particularly after the exercise immediately preceding a resting period, the protein is selectively taken up in the muscle tissue in the state where the process of protein assimilation is invigorated by the exercise, while the fat is combused as an energy source and consumed, with the resulting improvement in body

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composition contributing neatly to shape-up, body building, muscle increase and augmentation of the dynamic strength of muscles (Column 1, lines 55-68, Column 2, lines 1-64).

Goldberg et al. disclose that an increase in muscle weight reflects an increase in protein and results from greater protein synthesis and reduced protein breakdown and that hypertrophy leads to greater maximal tension development (Abstract).

Goldberg disclose that insulin reduces overall protein breakdown in skeletal muscle (Abstract).

Tabor discloses a dietary supplement which comprises a soy formulation and preferably comprising 70-90%, by weight, protein, 1-5%, by weight fat, and 1-25%, carbohydrate which may in the form of a powder or liquid form. The difference between the prior art and the claimed invention is that the Tabort does not expressly disclose a method of supplementing the diet of an athlete or supplementing the diet of a human by administering a dietary supplement which mimics or enhances insulin activity to enhance muscle size and strength.

However, the prior art amply suggests the same as Tabor discloses amounts of protein and carbohydrate which encompass or overlap the claimed amounts, Hastings discloses the incorporation of L-arginine, glutamine, carnitine, alanine, creatine, Miller discloses that whey proteins are effective in increasing lean body mass, muscle mass, Ostlund et al. disclose that pinitol and derivatives and metabolites thereof are useful in nutritional composition for treating conditions associated insulin resistance including complications arising from athletic activity, Ostland and Hastings discloses that compositions can be in the form of powders which can be mixed with a diluent such as water and Shimizu discloses that supplements can be administered to athletes or immediately after exercise. Further, the Goldberg references discloses that muscle hypertrophy can lead to greater maximal tension development and that muscle size is a reflection

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of increased protein synthesis and decreased protein breakdown and that insulin reduces overall protein breakdown in skeletal muscle tissue. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the use of said composition would increase muscle mass and strength.

The examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Applicant argues that there is no such thing as soy whey. The Applicants citation to various English language dictionaries (of which no copies have been provided) are insufficient to support the Applicant's argument. Contrary to the Applicant's arguments, the '166 patentee did not devise the term "soy whey". Whey in which the source is from soy is and has been clearly recognized in the art. See Goldsmith et al. and Bae et al.. The amendment, in any case, does not exclude soy whey as the claim is open ended. The claims do require that a protein be present that is from milk whey (which is suggested by Miller), however, the claims do not excluded other components, including other proteins sources, such as soy whey, as the claims are open ended. As such, Tabor and Hastings are not excluded as references.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

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Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
October 23, 2008

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616